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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HELM, CARALYNNE E

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,019	Applicant(s) LENDLEIN ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 2, 11-18 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 19 and 28 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/8/04, 12/20/04, 5/22/06, 8/22/06.

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DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

Applicant's election with traverse of group I and the species where the macromer is poly(ϵ -caprolactone) dimethacrylate and the additional macromer is poly(ethylene glycol) acrylate in the reply filed on August 22, 2008 is acknowledged. The traversal is on the grounds that no serious search burden exists. This is not found persuasive because the application recites a very large genus of methods and compositions. A wide collection of compositions are claimed that have some sort of active that are able to confer shape memory to hair. Different chemically structured shape memory polymers are known as well as an array of shape memory metals. A search of one type of shape memory material would not be coextensive with the other. A search for a hair forming method utilizing shape memory materials where one method requires a material with particular thermal properties and another requires a different set of properties is also quite expansive. Thus there would be an undue burden search were the inventions and species not separated

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 11-18, and 20-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention and species, there being no

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allowable generic or linking claim. Claims 12-18, 20-25, and 27 are withdrawn due to their presence in non-elected restriction groups. Claims 2 and 26 recite a method using a composition that comprises a macromer that comprises a thermoplastic segment that is not chemically crosslinkable. Neither of the elected macromers have such a segment since acrylates are chemically crosslinkable and poly(ethylene glycol) and poly(ϵ -caprolactone) are crosslinkable via irradiation. Thus claims 2 and 26 were withdrawn. Claim 11 recites a method that uses a composition with two actives that have no or weak shape memory properties alone then have a synergistically increased shape memory effect together. Applicant teaches that the poly(ϵ -caprolactone) dimethacrylate when applied to hair strands conferred a shape memory effect that was comparable to poly(ϵ -caprolactone) dimethacrylate together with poly(ethylene glycol) acrylate (see instant specification example 1, example 41, and page 51 lines 8-9). Since the elected macromers do not meet the recited limitation, claim 11 was withdrawn.

Claim Objections

Claim 10 is objected to because of the following informalities: it appears that an "s" was inadvertently added to the "glycol" in poly(ethylene-glycol)monoacrylate and an "o" was inadvertently omitted in "monoalkylethers". Appropriate correction is required.

Drawings

The drawings are objected to because the labeling of the figures contains misspelled words. Specifically, the word "figure" is misspelled in each title. Corrected

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drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 7-8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The phrase, "macromer having only one chemically reactive group" in claims 7 and 10, is used by the claim to mean "macromers with one easily reacted group (e.g. alkene, amine, etc.)", while the accepted meaning is "macromers with literally only one chemically reactive group". The term is indefinite because the specification does not clearly redefine the term. Further limitation of the claim that occurs in dependent claims recite monomers which include poly(ethylene glycol) acrylate, that are supposed to be part of this set. Polyethylene glycol has hydroxyl groups at both termini. Thus polyethylene acrylate would still contain a hydroxyl group on one end, which is a chemically reactive group. For the sake of application of prior art, the elected additional macromer is interpreted to meet the recited limitation.

Claims 4 recite that the at least one cross-linkable macromer "forms after crosslinking a shape memory polymer", then go on to further describe the macromers. The instant specification recites that that macromers are crosslinked in order to provide a shape memory polymer (see page 6 line 23-page 7 line 15). No description is provided to detail how the formation of the macromers occurs *after* a shape memory polymer is crosslinked (e.g. starting materials, reaction conditions, steps involved, etc.).

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Taken together, these recitations appear to be contradictory and are quite confusing. For the sake of application of prior art the process of generating the macromer is not interpreted to be a part of the claimed method.

Claim 3 recites the limitation " T_{trans} " in line 3. There is insufficient antecedent basis for this limitation in the claim since no temperatures were discussed in claim from which it depends.

The use of the terminology "monovalent" and/or "divalent" in claims 4 and 8 is unclear. Valence, according to the American Heritage Medical Dictionary, is the combining capacity of an atom or radical. In using monovalent or divalent to describe a polymer or organic residue, it is unclear what is encompassed. For example, it is not clear whether a methyl residue would be considered monovalent or tetravalent, since the atoms in its structure have the option of bonding to either one (hydrogen) or four (carbon) other atoms.

The description of the options from which the "macromer substitutes with only one chemically reactive group" is selected that are recited in claim 10 is confusing. It is unclear whether the "monoalkylethers thereof" means using monoalkylethers somehow made from poly(ethylene-glycol)monoacrylate and poly(propylene-glycol)monoacrylate or if poly(ethylene glycol) monoether and poly(propylene glycol) monoether were meant instead.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-10, 19, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. (US Patent No. 5,506,300) in view of Tatsuro et al. (Patent Abstracts of Japan 04-0414116 – see IDS), Herz et al. (US Patent No. 3,579,630), Lendlein et al. (WO99/42528 – see IDS – referred to henceforth as Lendlein et al. reference A), Lendlein et al. (Proceedings of the National Academy of Sciences 2001 98:842-847 – see IDS – referred to henceforth as Lendlein et al. reference B), and Dykstra et al. (US PGPub No. 2008/0057021).

The invention of the instant application involves two primary parts, 1) a method of changing the shape of hair after applying a shape memory composition and 2) poly(ϵ -caprolactone) dimethacrylate and poly(ethylene glycol) monoacrylate as the particular macromer combination in the shape memory composition. The concept and process of changing the shape of hair is made obvious by the teachings of Ward et al. in view of Tatsuro et al. and Herz et al. The combination of macromers present in the shape memory composition are made obvious by Lendlein et al. reference A in view of Lendlein et al. reference B and Dykstra et al. Discussion of the details of these references as well as the motivation to combine them is presented below.

Ward et al. teach the process of modifying the shape of doll hair that comprises a shape memory polymer (see column 12 line 51-column 13 line 44; instant claim 1). Here

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the polymer containing fiber is formed into a first shape and heated above its lower transition temperature (see column 13 lines 29-36). Subsequently the fiber is cooled and formed into a second shape (see column 13 lines 36-38; instant claims 3 and 19). Upon heating above the lower transition temperature, the fiber returns to the first shape (see column 13 lines 38-44; instant claim 28). Although Ward et al. teach the formation of the hair from the polymer, they do not teach the application of shape memory polymer to hair. Since it was known at the time of the invention that the form and shape of hair can be controllably altered due to the presence of shape memory polymers, it would have been obvious to one of ordinary skill to translate this method from synthetic hair to natural hair. Both Tatsuro et al. and Herz et al. teach the application of compositions comprising shape memory polymers to confer curl retention to styled natural hair (see Tatsuro et al. abstract and Herz et al. column 1 lines 64-68; instant claims 1 and 28). Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a shape memory polymer to hair and subject it to the shape changing method taught by Ward et al. Therefore the claimed method of changing the shape of hair after applying a shape memory composition is obvious over Ward et al. in view of Tatsuro et al. and Herz et al.

Ward et al. in view of Tatsuro et al. and Herz et al. do not teach a shape memory polymer composed of poly(ϵ -caprolactone) dimethacrylate and poly(ethylene glycol) monoacrylate macromers.

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Lendlein et al. reference A teach poly(ϵ -caprolactone) dimethacrylate as a shape memory polymer (see page 34 example 2 and page 37 shape memory properties section; instant claims 1 and 4-6). Lendlein et al. reference A goes on to teach the polymers of their invention for use in dolls and cosmetic compositions for human use (see page 28 lines 7 and 13). Lendlein et al. reference B teach this same polymer used as a macromer along with n-butyl acrylate, as a comonomer, to create a biocompatible shape memory polymer (see page 842 column 1 paragraph 4-column 2 line 2 and page 843 column 1 paragraph 1; instant claims 1 and 7). The comonomer is taught to confer softness to the final polymer, which is an attribute that would be desirable in a hair/cosmetic composition (see page 842 column 1 paragraph 4). Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to include poly(ϵ -caprolactone) dimethacrylate and n-butyl acrylate as monomers/macromers in a shape memory hair/cosmetic composition. Lendlein et al. reference A in view of Lendlein et al. reference B do not teach poly(ethylene glycol) monoacrylate as a comonomer (macromer) to include with poly(ϵ -caprolactone) dimethacrylate.

Dykstra et al. teach a personal care composition used on hair (see paragraph 20). Within this composition is taught a polymer where the monomers are selected from a set of non-cationic compounds (see paragraph 146; instant claims 7-10). In this set of monomers, poly(ethylene glycol) monoacrylate and n-butyl acrylate are equivalent choices. Since both these compounds are known for interchangeable use as monomers that compose a polymer in a hair composition and have a single acrylate group, it would

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have been obvious to one of ordinary skill in the art at the time the invention was made to use poly(ethylene glycol) monoacrylate instead of n-butyl acrylate in the composition of Lendlein et al. reference A in view of Lendlein et al. reference B. Therefore the claimed combination of poly(ϵ -caprolactone) dimethacrylate and poly(ethylene glycol) monoacrylate, as particular macromers in the shape memory composition, was obvious over Lendlein et al. reference A in view of Lendlein et al reference B and Dykstra.

Since the combination of poly(ϵ -caprolactone) dimethacrylate and poly(ethylene glycol) monoacrylate as macromers in shape memory hair/cosmetic composition was an obvious option, it would also have been obvious to use it in a method of changing the shape of hair after applying a shape memory composition. Therefore claims 1, 3-10, 19, and 28 are obvious over Ward et al. in view of Tatsuro et al., Herz et al., Lendlein et al reference A, Lendlein et al. reference B and Dykstra et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-10, 19, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 15 of copending Application No. 10/510873. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim the same method of treating and shaping hair where the same two classes of macromers are applied the hair. In particular, poly(ϵ -caprolactone) dimethacrylate and polyethylene glycol acrylate are both taught as the macromers. Further, both applications claim the cold forming of treated hair. Thus instant claims 1, 3-10, 19, and 26 are obvious over claims 1-10 and 15 of copending Application No. 10/510873.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615